PaceArt
Division of Data Critical Corporation
Special 510(k)
TX3 Cardiac Event Recorder

510(k) Summary

(1) Submitter Information

Name: PaceArt Division of Data Critical Corporation

Address: 81 Two Bridges Road
Fairfield, NJ 07004

Telephone Number: 973-439-9393

Contact Person: Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Rt. 17 S
Hasbrouck Heights, NJ 07604
201-727-1703
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Date Prepared: July 23, 2001

(2) Name of Device:

Trade Name: TX3 Cardiac Event recorder
Common Name: Cardiac Event Recorder
Classification Name: Transmitters and Receivers, Electrocardiograph, Telephone (74DXH)

(3) Equivalent legally-marketed device: Paceart Heart Access Plus Event Recorder K973141

(4) Description

The TX3 Cardiac Event Recorder is intended to record samples of a patient's electrocardiograph (ECG) when indicated by the patient, store the ECGs in a temporary storage, and then to be transmitted to a central station by the patient, by telephone. The unit has two modes: Post-event and Arrhythmia, or "Looping.". In post-event mode, the unit records a period of ECG following the pressing of a button by the patient. The unit can also determine the pulse duration of implanted pacemakers in Post-Event mode. In arrhythmia mode, the unit is a so-called "looping recorder:" it is always active, and thus records a sample of ECG both before and after the "patient event."

The unit records a 3-lead ECG, using four electrodes. Normally, the unit records the limb leads.

The Central Station unit is the Paceart WINCPTS 86-12 system (K915632).

The physician can program the unit and set the number of recordings and the duration of the recording that can be made before they must be transmitted to the central station.

(5) Intended Use

The TX3 Cardiac Event Recorder is intended to record samples of a patient's electrocardiograph (ECG) when indicated by the patient, store the ECGs in a temporary storage, and then to be transmitted to a central station by the patient, by telephone.

(b) Performance data

(1) Non-clinical tests

The TX3 and/or its predicate device have met the requirements of AAMI standard EC38.
The software has had extensive validition testing.

(2) Clinical tests

Not required.

(3) Conclusions

The TX3 Cardiac Event Recorder is equivalent in safety and efficacy to the legally-marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2001

Paceart, Inc.
c/o Dr. George Myers
Medsys, Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K012407
Trade Name: TX3 Cardiac Event Recorder
Regulation Number: 21 CFR 870.2929
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: July 27, 2001
Received: July 30, 2001

Dear Dr. Myers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K012407

Indications for Use Form

Device Name: TX3 Cardiac Event Recorder

Indications for Use:

The TX3 Cardiac Event Recorder, called the TX3, is intended to be worn by the patient and to record a short period of electrocardiogram when the patient depresses a button upon sensing symptoms indicated to him by his physician. It is indicated when such recordings are required for diagnosis. The intended patient population is patients experiencing intermittent and unexpected cardiac events and arrhythmias.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-the-Counter Use**_____
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012407